CLAIMS:

1. A process for producing a leukocyte bank suitable for CAT therapy comprising the steps of:
   (a) providing a blood sample from a healthy donor individual;
   (b) selectively separating and collecting leukocytes from the sample; and
   (c) selectively separating and collecting red blood cells and/or platelets and/or plasma from the sample; and
   (d) cryogenically preserving the leukocytes (and optionally the red blood cells and/or platelets and/or plasma);

wherein steps (b) and (c) are conducted with an automated leukapheresis device comprising a separation device (e.g. a centrifuge rotor or filter), a leukapheresis tubing set and one or more pumps for conveying the sample through the tubing set and the separated leukocytes into a collection vessel.

2. The process of claim 1 wherein the separated leukocytes are collected in a holding vessel.

3. The process of claim 2 further comprising the step of transferring two or more aliquots of the separated leukocytes collected in the holding vessel to two or more independent storage vessels, optionally wherein each of the independent storage vessels comprises a cryopreservation medium in fluid communication therewith.

4. The process of claim 3 wherein the storage vessels are double containment storage vessels.

5. The process of any one of claims 3 to 4 further comprising the step of mixing each aliquot of the separated leukocytes with a cryopreservation medium within each storage vessel.

6. The process of any one of the preceding claims further comprising the step of retrievably depositing the preserved leukocytes into two or more independent storage systems to produce a leukocyte bank which exhibits deposit redundancy.

7. The process of any one of the preceding claims wherein the separation and collection steps are conducted within a closed or functionally closed system.

8. The process of any one of the preceding claims wherein the separation and collection steps are applied iteratively to a series of blood samples from different healthy donor individuals.

9. The process of any one of the preceding claims further comprising the step of digitally storing information obtained from each donor individual in a digital information unit so as to permit matching of leukocyte deposit and donor for later autologous transplantation.

10. The process of any one of the preceding claims wherein the cryogenic preservation step (d) comprises freezing to a temperature at or below about -160°C.

11. The process of any one of claims 1 to 9 wherein the cryogenic preservation step (d) comprises freezing to a temperature at or below about -269°C.

12. The process of any one of claims 3 to 11 wherein the cryopropreservation medium comprises a penetrating cryoprotectant.

13. The process of claim 12 wherein the penetrating cryoprotectant comprises DMSO.

14. The process of claim 13 wherein the DMSO is present at a concentration of up to 10%.

15. The process of any one of claims 3 to 14 wherein cryopreservation medium further comprises an anticoagulant.

16. The process of claim 15 wherein the anticoagulant comprises an anticoagulant selected from acid citrate dextrose, EDTA and heparin.

17. The process of any one of claims 3 to 16 wherein the cryopreservation medium further comprises a nuclease.

18. The process of claim 17 wherein the nuclease comprises ribonuclease and/or deoxyribonuclease.

19. The process of any one of claims 3 to 18 wherein the cryopreservation medium further comprises a physiologically acceptable medium.

20. The process of claim 19 wherein the physiologically acceptable medium is phosphate buffered saline.

21. The process of any one of claims 3 to 20 wherein the cryopreservation medium further comprises a proteinaceous and/or sugar and/or polysaccharide composition.

22. The process of claim 21 wherein the proteinaceous composition comprises blood serum or a blood serum component.

23. The process of claim 22 wherein the proteinaceous composition comprises blood albumin (e.g. bovine serum albumin or human serum albumin).

24. The process of claim 23 wherein the proteinaceous composition comprises autologous blood serum separated and collected in step (c).

25. The process of any one of the preceding claims wherein the healthy donor individual:

(a) is predisposed to a leukocyte deficiency; and/or
(b) is not in remission from a leukocyte deficiency; and/or
(c) is juvenile, adolescent or adult; and/or
(d) is at risk of developing a leukocyte deficiency; and/or
(e) is a human individual between the ages of about 12 to 30 (e.g. 15 to 25); and/or
(f) has a fully-developed immune system.

26. The process of any one of the preceding claims wherein the blood sample is an isolated blood sample.

27. The process of claim 26 wherein the isolated blood sample has a volume of 450 to 500ml.

28. The process of any one of the preceding claims wherein steps (b) to (d) are applied iteratively to a series of blood samples from the same healthy donor individual.

29. The process of claim 28 wherein steps (b) to (d) are applied to 2-12 samples taken from the same healthy donor individual over the course of one year.

30. The process of any one of the preceding claims wherein the leukocytes separated in step (b) comprise (or consist essentially of): (a) granulocytes; and/or (b) lymphocytes; and/or (c) monocytes.

31. The process of claim 30 wherein the separation step (b) comprises the selective separation of a particular class or type of leukocyte.

32. The process of claim 31 wherein the separation step (b) comprises the selective separation of B-cells and/or T-cells and/or dendritic cells and/or mixtures thereof.

33. The process of any one of claims 9 to 32 wherein the information stored comprises:
(a) genetic information; and/or
(b) the date at which the blood sample was collected from the donor individual; and/or
(c) the age and sex of the donor individual; and/or
(d) the clinical status of the donor individual; and/or
(e) a medical history of the donor individual; and/or
(f) biographical data identifying the donor individual; and/or
(g) details of the processing and storage conditions used; and/or
(h) data identifying the person(s) responsible for processing the sample(s).

34. The process of claim 33 wherein the information comprises genetic information selected from:
(a) sequence information relating to one or more gene(s); and/or
(b) single nucleotide polymorphism (SNP) data; and/or
(c) a genetic fingerprint.

35. The process of any one of claims 9 to 34 wherein the digital information unit comprises at least one digital computer.

36. The process of any one of claims 3 to 35 further comprising the step of labelling the storage vessels with information sufficient to permit matching of the leukocyte deposit and donor.

37. The process of claim 36 wherein the information:
(a) describes the contents of the vessel (for example, sample size, number and/or volume); and/or

(b) identifies the leukocyte bank; and/or

(c) records the date at which the blood sample was collected from the donor individual; and/or

(d) comprises a statement that each package is for single patient use only; and/or

(e) comprises instructions for opening, aseptic presentation and further storage.

38. The process of claim 36 or 37 wherein the labelling comprises physical attachment of a bar code to the storage vessels.

39. The process of any one of the preceding claims wherein the leukocytes are treated:

(a) *in vivo* prior to provision of the blood sample;

(b) *in vitro* prior to separation step (b);

(c) *in vitro* after separation step (b) but prior to preservation step (d);

(d) *in vitro* after preservation step (d).

40. The process of any one of the preceding claims wherein the leukocytes are selectively separated and or collected from the sample by:

(a) isolated leukapheresis;

(b) continuous or interrupted flow centrifugation leukapheresis;

(c) continuous or interrupted flow filtration leukapheresis.

41. A process for producing a leukocyte composition suitable for CAT therapy comprising the steps of:

(e) producing a leukocyte cell bank by the process of any one of the preceding claims;

(f) matching the donor individual with a leukocyte deposit to identify an autologous leukocyte deposit (e.g. using the information as defined in any one of claims 9 to 40);

(g) retrieving a storage vessel containing an aliquot of preserved autologous leukocytes; and

(h) revitalizing the preserved autologous leukocytes to produce a leukocyte composition for autotransplantation into the donor individual.

42. The process of claim 41 wherein the leukocytes are revitalized by thawing and/or dilution.

43. The process of claim 41 or claim 42 for producing a leukocyte composition for restorative autotransplantation.

44. A leukocyte bank obtainable (or obtained) by the process of any one of claims 1 to 40.

45. A leukocyte composition obtainable (or obtained) by the process of any one of claims 41 to 43.

46. The leukocyte composition of claim 45 for use in therapy or prophylaxis (e.g. for CAT therapy).

47. Use of the leukocyte composition of claim 45 for the manufacture of a medicament for use in autotransplantation (e.g. in restorative autotransplantation).